REMARKS

Claims 6-8 have been previously cancelled. Claim 1 has been amended. Claims 1-5 and 9-10 are now pending in this application. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Rejection under 35 U.S.C. § 103(a)

Claims 1, 3, 4, 9, and 10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lurquin, et al. (Analytical Biochemistry (1975) 65: 1-10) in view of Vosbeck et al. (JBC (1973) 248(17): 6029-6034).

Claim 1 has been amended to recite the additional step of "amplifying an object DNA from the fraction containing nucleic acid acids by PCR". Support for the amendment is found in the present specification at page 11, section 3-3. The present claims are now clearly directed to a PCR application.

Neither Lurquin, et al. nor Vosbeck teach PCR. Lurquin, et al. (Analytical Biochemistry 65: 1-10 (1975)) teaches isolation of nucleic acid using a high salt concentration (2 M). Neither Lurquin, et al. nor Vosbeck (JBC 248 (17): 6029-6034 (1973) are concerned with PCR as PCR was not even known at the time of these two references. In particular, neither Lurquin, et al. nor Vosbeck teach "amplifying an object DNA from the fraction containing nucleic acid acids by PCR" as per amended claim 1. Accordingly, the combination of references does not teach all of the elements of the claimed invention.

Furthermore, the Examiner has acknowledged that Lurquin teaches adding NaCl to a final concentration of 2 M after the heating step rather than before the heating step as required by claim 1 but takes the position that "there is no particular reason for adding the sodium chloride before or after the heating step, and therefore, in the absence of unexpected results, the claimed order of addition is *prima facie* obvious" (Office Action (20081217), page 4, last paragraph).

In response, Applicants point out that nucleic acids are bound to histone proteins electrostatically and that it is critical to bring the sample to a salt concentration of 0.5 to 2 M ***before heating***.

In the present invention, nucleic acids dissociate slowly from histone proteins since high concentration of salt is added ***before heating***. After heating, histone proteins, which are already separation from nucleic acids, degenerate and aggregate and can be separated from nucleic acids.

On the other hand, in Lurquin, a high concentration of salt is added ***after heating***. After the solution is heated, histone proteins degenerate and aggregate and thus form complexes with nucleic acids included therein. Therefore, even if high concentration of salt is added after heating, nucleic acids cannot be separated from histone proteins. Accordingly, the method taught by Lurquin would not be effective to remove "PCR inhibitory substances" for "amplifying an object DNA from the fraction containing nucleic acid acids by PCR" as now claimed.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

The Examiner has rejected claim 2 as being unpatentable over Lurquin, et al. (Analytical Biochemistry (1975) 65: 1-10) in view of Vosbeck et al. (JBC (1973) 248(17): 6029-6034) and further in view of Wilson, et al. (U.S. 7,045,679B1). The Examiner asserts that it would have been obvious to one of ordinary skill in the art to substitute Triton X-100 as taught by Wilson, et al. for sarcosylate as taught by Lurquin, et al. However, since claim 2 depends from claim 1, which is neither taught nor suggested by Lurquin, et al. in view of Vosbeck et al., the invention defined in claim 2 is also patentably distinguished from the references, alone or in combination. Applicants respectfully request the withdrawal of the rejection.

Rejection under 35 U.S.C. § 103(a)

Claims 1-5, 9, and 10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Burdick, et al. (EP 0 393 744A1) in view of Akane, et al. (Biotechniques (1994) 16(2): 235,237,238).

Burdick, et al. teach isolation of nucleic acids from a sample using PCR. However, Burdick, et al. do not teach either the claimed salt concentration or gel filtration. Akane, et al. is cited in to show the use of gel filtration in PCR as a means to remove degraded DNA. Neither

reference teaches dissolving the sample in a buffer "wherein the salt concentration of the buffer is 0.5 to 2 M" as claimed.

The Examiner has argued that optimization of the salt concentration is routine optimization and not inventive.

However, as argued previously, Burdick would avoid high salt because it was known that high salt inhibits the polymerase. In support, Applicants previously provided a reference (Chien, et al. (1976) Journal of Bacteriology 127(3):1550).

The Examiner has countered that one of skill in the art would solve this problem, not by keeping the salt concentration low, but by diluting the sample (Office Action (20081217), page 9, last paragraph).

However, dilution of the sample to lower salt concentration also leads to a lower DNA concentration. An advantage of the claimed method is that a small sample can be used as discussed in the specification at page 11, last paragraph. However, if the purified nucleic acids must be diluted to remove the salt, then there is no incentive to use high salt to remove protein material as small sample volume cannot then be maintained and it is unlikely that one of ordinary skill in the art would resort to high salt for removal of protein knowing that the high salt concentration would later be troublesome for PCR and that dilution of the sample would be needed.

Regarding arguments as to the criticality of the salt concentration to the practice of the claimed invention, the Examiner found the arguments unpersuasive because the claims were not commensurate in scope and argued that the claimed methods did not require that the isolated nucleic acids obtained after gel filtration be used in PCR amplification (Office Action, page 11, last paragraph). The Examiner further points out that Burdick teaches that amplification is not the only downstream use of nucleic acids obtained by the extraction method (Office Action, page 12, first paragraph).

In response, claim 1 is amended to recite the additional step of "amplifying an object DNA from the fraction containing nucleic acid acids by PCR". Support for the amendment is found in the present specification at page 11, section 3-3. The present claims are now clearly directed to a PCR application. Reconsideration is respectfully requested.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

The Examiner is referred to the listing of cases submitted with the RCE of February 27, 2008.

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: March 24, 2009

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